

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|------------|---|------------------|---------------|
| In re:     | Hung et al.                                     | Confirmation No. | 8506          |
| Appl. No.: | 10/825,752                                      | Group Art Unit:  | 3764          |
| Filed:     | April 16, 2004                                  | Examiner:        | Michael Brown |
| For:       | INCREASING RETRIEVABLE CELLS FROM A BREAST DUCT |                  |               |

June 20, 2008

APPEAL BRIEF

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed April 7, 2008. It contains the following items in the order indicated below, as required by C.F.R. §41.37:

- I. Real Party in Interest
- II. Related Appeals and Interferences
- III. Status of Claims
- IV. Status of Amendments
- V. Summary of Claimed Subject Matter
- VI. Grounds of Rejection to be Reviewed on Appeal
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- VIII. Conclusion
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**I. Real Party in Interest.**

The real party in interest in this appeal is Cytoc Corporation, Inc., the assignee of the above-referenced patent application.

**II. Related Appeals and Interferences.**

There are no related appeals and/or interferences involving this application or its subject matter.

**III. Status of Claims.**

Claims 1, 2, 4, and 5 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,413,228 (“Hung”) in view of U.S. Patent No. 4,740,196 (“Powell”), U.S. Patent No. 6,054,314 (“Kim”), and U.S. Patent No. 6,221,622 (“Love”). The claims appear in Appendix A. No other claims are pending. Claim 3 has been previously cancelled.

**IV. Status of Amendments.**

All of Appellants’ amendments have been entered.

**V. Summary of the Claimed Subject Matter.**

Although the invention should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of certain embodiments in order to aid in understanding the invention.

Independent claim 1 is directed to a method for increasing the retrievable cell amount in a breast duct comprising the steps of: applying vibration internally to a breast duct sufficient to induce cell sloughing within said breast duct and; collecting said sloughed cells from said breast duct; wherein applying vibration to said breast duct increases the retrievable amount of cells collected from said breast duct. A summary of the invention may be found at page 12, lines 10 to 26 of the specification and Figures 1-3.

**VI. Grounds of Rejection to be Reviewed on Appeal.**

**Issue 1--**Whether claims 1, 2, 4, and 5 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,413,228 (“Hung”) in view of U.S. Patent No. 4,740,196 (“Powell”), U.S. Patent No. 6,054,314 (“Kim”), and U.S. Patent No. 6,221,622 (“Love”).

## VII. Argument

**Issue 1-** Whether claims 1, 2, 4, and 5 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,413,228 (“Hung”) in view of U.S. Patent No. 4,740,196 (“Powell”), U.S. Patent No. 6,054,314 (“Kim”), and U.S. Patent No. 6,221,622 (“Love”).

The Examiner has rejected Appellants’ claims 1, 2, 4, and 5 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,413,228 (“Hung”) in view of U.S. Patent No. 4,740,196 (“Powell”), U.S. Patent No. 6,054,314 (“Kim”), and U.S. Patent No. 6,221,622 (“Love”).

### Claim 1

The Examiner has rejected Appellants’ claim 1 under 35 U.S.C. 103(a) as being unpatentable over Hung in view of Powell, Kim and Love. The Appellants respectfully disagree that claim 1 is rendered obvious by Hung in view of Powell, Kim and Love. The Examiner has failed to establish a *prima facie* case of obviousness, since Hung and Powell, Kim and Love; either alone or in combination, fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention. See, e.g., *Carella v Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

A new combination of elements can be patented "whether it be composed of elements all new, partly new or all old." *Rosmount, Inc. v Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

"[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

*Dembiczak* involved patent claims to "a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern." *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to Dembiczak; and prior art "conventional" plastic lawn or trash

bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." Sibia Neurosciences, Inc. v. Cadus Pharma. Corp., 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); Tec Air, Inc. v. Denso Mfg., Inc., 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).

... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," Clearstream Wastewater Sys. v. Hydro-Action, Inc., 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings in the applied references in the proposed manner to arrive at the invention of claim 1. The motivation cited in the Office Action for the proposed combination is as follows:

“...It would have been obvious to one of ordinary skill in the art at the time that the invention was made that vibration as taught by Powell and Kim could be substituted for massaging as disclosed by Hung because vibration or massaging can be used to stimulate the breast and cause cells to come from the breast.”

(January 1, 2008 Final Office Action; page 2, last paragraph).

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required. The Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to use a method for increasing a retrievable cell amount in a breast duct by applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and collecting the sloughed cells from the breast duct wherein applying vibration to the breast duct increases the retrievable amount of cells collected from the breast duct as described in claim 1.

Hung does not teach or suggest the use of vibration to increase the retrievable amount of cells collected from a breast duct. The deficiency of Hung cannot be made up by Powell, Kim and Love. The assertion by the Examiner that massaging, vibrating and applying a vacuum to the body are equivalent is not supported by any evidence and is demonstrably false. Massaging a breast and applying a vacuum to a breast duct as described in Love and Hung are methods of retrieving ductal

wash fluid infused into the breast duct of a patient in order to obtain ductal cells. Nowhere in Love or Hung

The Examiner argues that massaging, vibrating and applying a vacuum to the body are used to increase the flow of fluid from the breast and therefore the amount of cells collected (Final Office Action, page 3).

The force exerted by a massage is very different than the force exerted by vibration. While massage may be able to manipulate breast ducts close to the surface of the breast, vibration such as ultrasound can penetrate deep into the breast tissue to reach those ducts which would not be accessible through massage. The Appellant would point out that claim 1 recites a method for applying vibration internally to a breast duct to increase the retrievable amount of cells collected from the breast duct. Since vibration can reach breast ducts not accessible by massage, the application of vibration to breast duct in order to specifically increase cell sloughing would be a non-obvious improvement over previous methods of increasing the cellular content collected from breast ducts. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. The Examiner has not pointed to any clear, particular motivation in the references to reach the claimed invention.

Thus, a *prima facie* case of obviousness has not been established because the Examiner has not presented evidence that one having ordinary skill in the art would have been motivated to combine Hung, Powell, Kim and Love to make the claimed invention. In view of the foregoing, the rejection of claim 1 under U.S.C. § 103(a), should be reversed.



Dependent Claims 2, 3, and 5

Dependent claims 2, 3, and 5 incorporate all of the elements of Claim 1 from which they depend and add novel and non-obvious limitations thereto. Thus, dependent claims 2, 3, and 5 are patentable over Hung, Powell, Kim and Love for at least the same reasons set forth herein. See *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.")

**IX. Conclusion**

In view of the arguments presented above, the Appellants contend that each of claims 1, 2, 3, and 5 are patentable. Therefore, reversal of the rejections under 35 U.S.C. §103(a) is respectfully solicited.

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Respectfully submitted,



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**X. Appendix of Claims Involved in the Appeal**

1. A method for increasing a retrievable cell amount in a breast duct comprising the steps of:  
applying vibration internally to a breast duct sufficient to induce cell sloughing within said breast duct and;  
collecting said sloughed cells from said breast duct;  
wherein applying vibration to said breast duct increases the retrievable amount of cells collected from said breast duct.
2. A method as in claim 1, wherein said vibration is produced by ultrasound.
3. (canceled)
4. A method as in claim 1, wherein said vibration is combined with heat and/or massage.
5. A method as in claim 1, wherein said retrievable cell amount is collected through ductal lavage.

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**XI. Evidence Appendix**

NONE

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X. Related Proceedings Appendix

NONE